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Teresa Stanek Rea  
Burns Doane Swecker & Mathis LLP  
PO Box 1404  
Alexandria VA 22313-1404

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,446,194

**MAILED**

**MAR 31 2005**

Dear Ms. Rea:

**REEXAM UNIT**

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,446,194 for a period of 416 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:  
<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>  
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at [Karin.Ferriter@uspto.gov](mailto:Karin.Ferriter@uspto.gov) by e-mail.

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

Attention: Claudia Grillo

RE: COMTAN®  
FDA Docket No.: 00E-1344

# UNITED STATES PATENT AND TRADEMARK OFFICE

## (12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 5,446,194  
(45) ISSUED : August 29, 1995  
(75) INVENTOR : Reijo J. Bäckström, et al.  
(73) PATENT OWNER : Orion-yhtymä Oy  
(95) PRODUCT : COMTAN® (entacapone)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,446,194 based upon the regulatory review of the product COMTAN® (entacapone) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 416 days

from August 29, 2012, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 29th day of March 2005.

A handwritten signature in black ink, reading "Jon W. Dudas", written over a circular stamp.

Jon W. Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office